



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: 2025 G STREET, N.W., SUITE 200
Washington, D.C. 20423
www.uspto.gov

APPLICATION NO.	FILED DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/760,156	01/12/2001	Donald Lee Morrow	1365	2341

27310 7800 07/16/2002

PIONEER HI-BRED INTERNATIONAL INC.
7100 N.W. 62ND AVENUE
P.O. BOX 1000
JOHNSTON, IA 50131

[REDACTED] EXAMINER

KRUSE, DAVID H

[REDACTED] ART UNIT [REDACTED] PAPER NUMBER

1638

DATE MAILED: 07/16/2002

4

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/760,156

Applicant(s)

MORROW, DONALD LEE

Examiner

David H Kruse

Art Unit

1638

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on _____.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-49 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-49 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All
 - b) Some *
 - c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
 - a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2 . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Information Disclosure Statement

1. The information disclosure statement filed 26 March 2001 has been considered, a copy of which is attached hereto.

Specification

2. The disclosure is objected to because of the following informalities: On page 52, there is no indication of the ATCC Accession Number for the deposited PH5DR inbred maize line.

Appropriate correction is required.

Claim Objections

3. Claims 1, 6, 21, 24, 25, 37 and 40 are objected to because of the following informalities:

At claims 1, 6, 21, 25, 37 and 40 the ATCC Accession Number has been left blank.

At claims 5 and 24, the phrase "A tissue culture" should read -- The tissue culture -- in referring to claims 4 and 23 respectively.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. § 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Art Unit: 1638

5. Claims 1-49 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-49 are indefinite because the designation "PH5DR" does not denote an art recognized designation of a maize plant and hence does not state the metes and bounds of the claimed invention. The ATCC Accession Number must be filled in where appropriate to clearly provide the identifying characteristics of Applicant's maize hybrid line designated PH5DR. Compliance with this requirement may be held in abeyance since Applicant's specification provides evidence that the deposit has been or will be made. Applicant must provide the appropriate amendment to insert the deposit information at the time of allowance in both the specification and the claims.

Claim 3 is indefinite because the plant of claim 2 is not male sterile. Amending said claim to replace "is male sterile" with -- further comprises a genetic factor conferring male sterility -- would obviate this rejection.

At claims 5 and 24, lines 1-2, the phrase "the cells or protoplasts being from a tissue" is indefinite because it is unclear what the metes and bounds of "being from" are. In addition, the term "protoplasts" lacks a proper antecedent basis in the claim. It is suggested that the phrase read -- the cells or protoplasts of said cells having been isolated from a tissue --.

At claim 6, lines 1-2, the phrase "capable of expressing" is indefinite and does not state a positive feature of the regenerated plants, the phrase should read -- that expresses --.

Claims 14, 33, 41, 45 and 46 are indefinite because the phrases "high grain yield", "good overall disease resistance" and "above average test weight", for example, are relative and do not state the metes and bounds of the claimed invention.

Claims 15 and 34 are indefinite because the claims do not set forth any positive method steps leading to the maize plant at line 1 of the claims. Hence, it is unclear what the metes and bounds of the claimed methods are.

Claims 16 and 35 are indefinite because they are drawn to a "maize plant breeding program" while the claims to which they depend are drawn to a method. Appropriate correction is required.

Claims 19 and 20 are indefinite because said claims are directed to a single gene conversion while the claim to which they depend is drawn to maize plants. Appropriate correction is required.

Claim 22 is indefinite because the plant of claim 21 is not male sterile. Amending said claim to replace "is male sterile" with -- further comprises a genetic factor conferring male sterility -- would obviate this rejection.

At claims 40-46, the phrase "derived maize plant" is indefinite because it is unclear what the metes and bounds of the limitation "derived" are. In addition, it is unclear what the metes and bounds of the phrase "further derived" at claim 43 or the phrase "derived progeny" at claim 44 are.

Claim 44 is indefinite because it is unclear where in the method of claim 40 plant tissue culture methods are utilized, what the metes and bounds of "utilizing" said methods are, and how "derived progeny" are produced "utilizing" plant tissue culture

Art Unit: 1638

methods. The claim is, in general, narrative and does not denote a positive method step.

Claims 48 and 49 are indefinite because said claims are directed to a single gene conversion while the claim to which they depend is drawn to maize plants. Appropriate correction is required.

6. The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 9-11, 13, 14, 17-20, 28-30, 32, 33, 36, 41, 43 and 45-49 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claimed invention lacks written description under current written description guidelines. The claims are drawn to maize progeny plants and transgenic maize plants having undisclosed identifying characteristics whereby only the characteristics of the deposited maize line PH5DR are known. There are insufficient relevant identifying characteristics to allow one skilled in the art to predictably determine the genomic structure or phenotypic characteristics of the plant obtained at each level of crossing or at each generation. In addition, at claims 11, 13, 18-20, 30, 32 and 47-49, the effect of transgenes and/or single gene conversions on the physiological and morphological characteristic of a transgenic PH5DR maize plant or progeny thereof, is not sufficiently

Art Unit: 1638

described whereby one of skill in the art could recognize the claimed maize plant. The breeding techniques encompass recurrent selection, backcrossing, pedigree breeding, restriction fragment length polymorphism enhanced selection, genetic marker enhanced selection and transformation and combinations thereof. Each of these breeding techniques would result in a structurally and phenotypically different maize plant. Over an undetermined number of generations, the identifying characteristics of each generation become highly unpredictable, especially in view of the fact that none of the identifying characteristics of the progeny plants are disclosed in the specification. While claims 14, 33, 41, 45 and 46 set forth at least two PH5DR traits, because the terms used to describe the traits are relative terms, lacking a comparative basis (see 112, second paragraph rejection above), these traits do not adequately define or distinguish PH5DR progeny maize plants. Furthermore, neither the individual traits themselves, nor their degree of expression, appear to be unique to the deposited maize line PH5DR. Accordingly, there is a lack of adequate description of the claimed progeny maize plants. In view of the level of knowledge and skill in the art, one skilled in the art would not recognize from the disclosure that Applicant was in possession of the claimed invention at the time of filing. Hence, the claimed invention lacks adequate written description under current written description guidelines (see Written Description Requirement published in Federal Register/ Vol. 66, No. 4/ Friday 5, 2001/ Notices; p. 1099-1111).

8. Claims 12, 31 and 42 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as

to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Because Applicant has failed to adequately describe the maize plants at claims 11, 30 and 41 the methods for producing a maize plant of the instant claims are not enabled. One skilled in the art would not know how to use a plant that has not been adequately described in a method of producing a maize plant, regardless of the technique used.

Claim Rejections - 35 USC § 102/103

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

11. Claims 9, 10, 14, 17, 28, 29, 33, 36, 41, 43, 45 and 46 are rejected under 35 U.S.C. § 102(b) as anticipated by or, in the alternative, under 35 U.S.C. § 103(a) as obvious over Segebart (US Patent 5,367,109).

Segebart discloses an inbred maize line designated PHHB9 (see claim 1), which Applicant admits is comparable to the inbred maize line of the instant invention (see page 36, paragraph 4 of the instant application). Said PHHB9 inbred maize line

inherently discloses such relative traits as "high grain yield", "above average test weight" and "good overall disease resistance" (see for example, Table 2D of the instant specification). Applicant should also note that because the limitations set forth in the claims lack a comparative basis as set forth in the 112 second paragraph rejection above, these limitations are interpreted by the Office to be identical to those taught by Segebart in the instant reference. While the inbred maize line of Segebart is designated PHHB9 and the parent maize variety of the instant claims is designated PH5DR, there are insufficient identifying characteristics set forth in the claims to distinguish the claimed plants from those of the prior art.

Segebart does not specifically disclose a method of producing maize plants using PH5DR as a parent in an unspecified number of crosses with unspecified second parents.

The hybrid corn seed and hybrid maize plant of claims 9 and 10 would have been *prima facie* obvious to one of ordinary skill in the art at the time of applicant's invention because, depending upon what second inbred maize plant one of skill in the art had selected, the resulting maize seed and progeny could be genetically, morphologically and physiologically indistinguishable from that of the instant claims. Similarly, the maize plant of claims 14, 33 and 36 and the F1 hybrid seed and plant of claims 28 and 29 would have been obvious in view of the teachings of the Segebart reference. The PH5DR-derived corn plant of claims 41, 43, 45 and 46 would also have been obvious in view of the Segebart reference because again, depending upon what second corn plant one of skill selects in producing said "derived" corn plant, the resulting progeny could be

Art Unit: 1638

genetically, physiologically and morphologically indistinguishable from that of the claimed PH5DR-derived corn plant, given the loss of PH5DR-derived genetic material with each outcross to a non-PH5DR parent. See *In re Thorpe*, 227 USPQ 964, 966 (Fed. Cir. 1985), which teaches that a product-by-process claim may be properly rejectable over prior art teaching the same product produced by a different process, if the process of making the product fails to distinguish the two products.

Conclusion

12. No claims are allowed

13. Claims 1-8, 11-13, 15, 16, 18-27, 30, 31, 32, 34, 35, 37-40, 42, 44 and 47-49 appear to be free of the prior art because it neither suggests nor teaches the PH5DR inbred maize plant or a maize plant having all of the morphological and physiological characteristics of the PH5DR inbred maize plant of the instant claims or methods of use.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David H. Kruse, Ph.D. whose telephone number is (703) 306-4539. The examiner can normally be reached on Monday to Friday from 8:00 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Amy Nelson can be reached at (703) 306-3218. The fax telephone number for this Group is (703) 872-9306 Before Final or (703) 872-9307 After Final.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Kim Davis whose telephone number is (703) 305-3015.

DAVID T. FOX
PRIMARY EXAMINER

David H. Kruse, Ph.D.

10 July 2002

GROUP 100/638

David T. Fox